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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/761,387 | 01/22/2004 | Dennis M. Vigil | 12013/47103 | 2425 |

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KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

EXAMINER

MCCORKLE, MELISSA A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3763

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 10/761,387 | Applicant(s) VIGIL ET AL. | |
| | Examiner Melissa A. McCorkle | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 9, 10, 12-14, 17, 19-23, 26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 9, 10, 12-14, 17, 19-23, 26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of: .
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/22/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. In response to applicant's telephone inquiry regarding the last Office action, the following corrective action is taken.

The period for reply of 3 MONTHS set in said Office Action is restarted to begin with the mailing date of this letter.

Double Patenting

1. Claims 1-4, 7, 9-10, 12-14, 17, 19-23, 26 & 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 8, 10, 12-14, 16, 18, 20-23, 25, 27 of U.S. Patent No. 6,695,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims would be obvious over the currently pending claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 4, 10, 12, 14, 20, 21 are 23 are rejected under 35 U.S.C. 102(b) as being anticipated by March et al (5,306,250.) March discloses a method for releasing fluid medicaments into a vessel wall of a patient at a treatment site, the method comprising the steps of providing an expanding member 46 defining an axis and having a plurality of dispensers 48 mounted on said expanding member for movement therewith, said dispensers consisting only of dispensers positioned in a single plane

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oriented substantially perpendicular to said axis [fig 7]; advancing said expanding member through the vessel to the site; moving said expanding member between a first configuration [fig 2] wherein said dispensers are positioned substantially adjacent of said expanding member, and a second configuration [fig 3] wherein said dispensers are radially extended from said axis penetrating into the vessel wall; and providing a fluid medicament and releasing said fluid medicament through said dispensers into the vessel wall for substantially circumferential dispersion of said fluid medicament into said vessel wall [column 5 line 55 – col 6 line 54, and claim 1; furthermore it is inherent to provide an object if all structural limitations are met];

4. wherein said fluid medicament inhibits the proliferation of smooth tissue growth in the vessel [col1 line 35, furthermore since all structural limitations are met it is inherent that the device will function as claimed];

5. wherein said fluid medicament stimulates the production of collateral vessels [col 1 line 30, furthermore since all structural limitations are met it is inherent that the device will function as claimed].

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3, 13, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over March et al in view of Wilcox et al (5,681,289.) March discloses all of applicant's basic inventive concept of a method of delivering medication into an arterial wall with the exception of the fluid medicament comprising a radioactive isotope. Wilcox shows this feature to be old in the medical delivery devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use a radioactive isotope in the delivery device for the well-known purpose of providing for infection and pain control (column 1 lines 15).

9. Claims 7, 9, 17, 19, 26, & 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over March in view of Nabel et al (5,328,470.) March discloses all of applicant's basic inventive concept of a method of delivery medication into an arterial wall with the exception of the fluid medicament comprising a binder which binds to at least a portion of the vessel wall, or wherein said fluid medicament comprises a gene for gene therapy. Nabel shows these features to be old in the medical delivery devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's

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invention to have the medicament comprise a gene or a binder for the purpose of treating the specific diseases that these medicaments treat [see col 8 lines 8-46].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Melissa A. McCorkle
Examiner
Art Unit 3763

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Examiner
Art Unit 3763